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Foreign Agricultural Service

GAIN Global Agricultural Information Network

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Report Name: European Commission Opens Feedback Period On List of Antimicrobials Reserved for Human Medicine

Country: European Union

Post: Brussels USEU

Report Category: Livestock and Products, Sanitary/Phytosanitary/Food Safety

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Report Highlights:

The long-awaited EU proposed list of antimicrobial products reserved for human medicine has been published for comment through May 17, 2022. This Commission Implementing Regulation is part of the implementation legislation for the Veterinary Medicinal Products Regulation (EU) 2019/6, which was implemented on January 28, 2022. After the feedback period closes, the European Commission and the Member States must approve the final draft regulation, which could possibly be published in the EU Official Journal during the summer of 2022 at the earliest. Article 118 of the Veterinary Medicinal Products Regulation will extend this restriction on the use of reserved antimicrobial products to imported animal products.

On April 19, 2022, the European Commission (EC) opened a 4-week feedback period through May 17, 2022 on its draft implementing regulation and annex for the list of antimicrobial products reserved for human medicine on its "Have Your Say" platform. This Commission Implementing Regulation is part of the implementation legislation for the Veterinary Medicinal Products Regulation (EU) 2019/6, which was implemented on January 28, 2022.

U.S. stakeholders who would like to comment can do so at the following link:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11653-Drug-resistance-list-of-antimicrobial-medicines-reserved-for-treating-humans_en
Note: The deadline for input is 12:00 a.m. (Central European Summer Time or Universal Time Coordinated + 01:00) on May 17, 2022. Please note that all comments made could become public.

The list of antimicrobial products in the draft annex, which will be reserved for human medicine only, reflects the Advised List that the EC had requested from the European Medicines Agency (EMA). The suggested implementation time in the draft implementing regulation has been set at 6 months.

Background:

In December 2018, the EU agreed on an overhaul of the rules on the authorization and use of veterinary medicines in the European Union (EU) in the Veterinary Medicinal Products Regulation (EU) 2019/6. As part of this regulation, the EC aims to fight antimicrobial resistance (AMR) by preserving some antimicrobial products exclusively for human medicine. As the European Parliament and the Council of the EU amended the original regulation draft by adding an extraterritoriality clause through Article 118, these two pieces of the implementation legislation of the Veterinary Medicinal Products Regulation were delayed and missed the implementation deadline of January 28, 2022. The current proposal will set the list of microbial products reserved for human medicine, while the implementing act for Article 118 is expected to follow soon.

Next Steps:

After the feedback period closes, the EC may need several weeks to address the comments before finalizing the draft implementing regulation for adoption by the College of Commissioners. The formal regulation proposal may then be put on the agenda for discussion and vote in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), possibly for the June 9-10 or July 6-7 meetings. After the necessary legal scrubbing and translation, the final Implementing Regulation could then be published in the EU Official Journal during or after the summer.

Attachments:

No Attachments.